

## **REMARKS**

Claims 41-42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-93 are pending, wherein claims 41, 44, 45, 59, 65, 72, 77, 81, 86 and 91-93 have been amended and claims 55, 64 and 69 were cancelled. Reconsideration and allowance for the above-identified application are now respectfully requested.

### **I. ART REJECTION**

The Office Action rejects claims 41-42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-93 under 35 U.S.C. § 103(a) as being unpatentable over McLaughlin (US 6,108,850) and Shimada et al. (US 5,626,837). In response, Applicants have amended the independent claims in a manner that is believed to distinguish over McLaughlin, which discloses an abrasive toothpaste composition, and Shimada, which was only cited for the teaching regarding antimicrobial agents in a dental composition. The independent claims claim a dental bleaching composition free of abrasives comprised of a dental bleaching agent, potassium nitrate and an abrasive-free carrier into which the dental bleaching agent and potassium nitrate are dispersed. The Examiner acknowledges that dental bleaching compositions that are free of abrasives are patentable over McLaughlin and Shimada. Office Action, page 5 (“claims 55, 64 and 69 exclude abrasives from the instant composition and these claims would be allowable once added to the independent claims”).

### **II. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION**

The Office Action rejects claims 41-42, 44-48, 50-87 and 91-93 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,306,370 (“’370 patent”). In response, Applicants will show that claims 41-42, 44-48, 50-87 and 91-93 (“instant claims”) of the Application are unobvious over claims 1-23 of the ‘370 patent because the instant claims are directed to dental bleaching compositions that demonstrate unexpected results relative to reduced oral sensitivity.

In making the rejection, the Examiner begins by stating that the ‘370 patent “claims a composition comprising 3-20% peroxides such as carbamide peroxide and hydrogen peroxide plus 0.1-10% potassium nitrate”. Office Action, page 6. Thereafter, the Examiner agrees that Applicants have successfully demonstrated unexpected results relative to the narrowly tailored claimed ranges for potassium nitrate:

Applicant points out in a declaration and a working example that 10.5% and 15% carbamide peroxide plus 0.5% potassium nitrate yields unexpected data. Applicant also refers Examiner to examples 3-10 in instant specification, which suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is in agreement with Applicant's results. However, the Examiner argues that the declaration is not commensurate in scope with the claims because the claims recite a range of 3-30% peroxide and applicants' declaration only shows ranges of peroxide being 10% or 15%.

Office Action, pages 6-7 (emphasis added).

Applicants first wish to point out that the comparative study was done solely to determine the amount of potassium nitrate that works best in reducing sensitivity. It was not aimed at testing different concentrations of peroxide bleaching agent because the amounts of peroxide used in the industry are well known and commonly used throughout the ranges claimed in the present application. Determining an optimum quantity of bleaching agent was simply not the purpose of the study. If one had studied different amounts of bleaching agent, one would see from the test results that going from 10% bleach to 15% had almost no effect on sensitivity. In contrast, reducing the amount of potassium nitrate to well below 3% caused a dramatic decrease in sensitivity, which is surprising and unexpected as using less potassium resulted in a greater desensitizing effect.

In view of the Examiner's statement quoted above, the issue is not whether the claimed ranges of potassium nitrate (*i.e.*, about 0.01-2%, about 0.5-1%, or about 0.5%) are sufficiently narrow but rather the claimed ranges of dental bleaching agent. The Examiner is in agreement that the results of the comparative study and Examples 3-10 show that even the broadest narrowly tailored range of about 0.01-2% would be expected to provide unexpectedly superior results relative to reducing sensitivity. Therefore, the sole remaining issue is whether the claims are sufficiently narrowly tailored relative to the quantity of dental bleaching agent. More particularly, the sole issue is whether the test data, which show unexpectedly superior results relative to reduced sensitivity at a bleaching agent concentration of 10.5%, support the ranges recited in the claims, namely 10% to about 30%, 10% to about 20%, and 10% to 15% dental bleaching agent.

First, Applicants reproduce below the results of the comparative study, which compared sensitivity relative to five different compositions and which is set forth in the Application at pages 26-28 and also in the Declaration of Dan E. Fischer, DDS filed together with Amendment “B” on November 21, 2002. The different test samples were labeled as compositions A-E and include the following amounts of dental bleaching agent and potassium nitrate:

<u>Composition</u>	<u>Carbamide Peroxide</u>	<u>KNO<sub>3</sub></u>
A	10%	0%
B	10%	3%
C	10%	3%
D	15%	3%
E	10.5%	0.5%

The sensitivity results are set forth in Table 1 as follows, which is found in both the Application and the Fischer Declaration:

Table 1

1	2	3	4	5	6	7	8	9
A	266	37 (13.9)	40 (15)	2 (0.8)	3 (1.1)	14	7	5.4
B	294	51 (17.3)	50 (17)	14 (4.8)	3 (1)	17	6	4.6
C	279	65 (23.3)	45 (16.1)	4 (1.4)	3 (1.1)	17	6	6.7
D	256	61 (23.9)	70 (27.6)	13 (5.1)	2 (0.8)	18	2	7.5
E	216	14 (5.3)	4 (2.1)	0 (0)	0 (0)	7	11	8.6

Column 1 = Composition Tested

Column 2 = Total number of days used by all patients in group

Column 3 = Number of days sensitive to hot or cold (% of total days)

Column 4 = Number of days gums sensitive (% of total days)

Column 5 = Number of days tongue sensitive (% of total days)

Column 6 = Number of days throat sensitive (% of total days)

Column 7 = Number of patients reporting sensitivity to anything

Column 8 = Number of patients reporting no sensitivity to anything

Column 9 = Average number of shade tab changes

The first and most surprising statistic that relates to the patentability of the claims is that compositions B-C, which included 3% potassium nitrate, resulted in slightly greater sensitivity than composition A, which included no potassium nitrate. On the other hand, composition E, which only included 0.5% potassium nitrate, resulted in a dramatic decrease in sensitivity. These results are surprising and unexpected because increasing the amount of potassium nitrate, a desensitizing agent, from 0.5% to 3% would be expected to further reduce sensitivity beyond that provided when only 0.5% is included. In fact, sensitivity went up, which is counterintuitive. Moreover, when 3% potassium nitrate was included, sensitivity was similar to or greater than when no potassium nitrate was included. That is also a surprising result. Both results support the patentability of the instant claims, which claim narrowly tailored ranges of potassium nitrate, over the claims of the '370 patent, which discloses a broader range and assumes that increasing the amount of potassium nitrate will result in decreased sensitivity. In fact, the most preferred range disclosed in the '370 patent (about 3-10%) (col. 6, lines 57-59) lies wholly outside every claimed range in the instant Application (*i.e.*, about 0.01-2%, about 0.05-1%, and about 0.5%). That indicates that the inventors of the '370 patent failed to recognize the benefits of using less potassium nitrate, not more, when formulating a dental bleaching composition having reduced sensitivity.

According to the court in *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003), “a *prima facie* case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art.” However, the court went on to say that “an applicant may overcome a *prima facie* case of obviousness by establishing ‘that the [claimed] range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.’” *Id.* at 1330. “[T]he applicant’s showing of unexpected results must be commensurate in scope with the claimed range.” *Id.*

In the present case, the examples contained in the Application and included in the comparative study as well as prophetic Examples 3-10 establish that the narrowly tailored ranges

for potassium nitrate (*i.e.*, about 0.01-2%, about 0.05-1%, and about 0.5%) are commensurate in scope with the test data showing unexpected results. The claimed ranges of potassium nitrate include amounts greater than 0% and significantly less than 3% potassium nitrate and include the amounts set forth in Examples 3-10 (*i.e.*, 0.01%, 0.05%, 0.1%, 0.5%, 0.75%, 1%, 1.5% and 2%). Although the Office Action contains seemingly contradictory statements regarding whether the comparative test data support the broad, intermediate and narrow ranges for potassium nitrate, the statement from the Office Action at pages 6-7 quoted above indicates the Examiner does not have a problem with the three ranges for potassium nitrate, only the ranges for the bleaching agent. The sole issue appears to be whether the claimed amounts of bleaching agent are commensurate in scope with the results of the comparative test.

In support of Applicants' position that the test data adequately supports the narrow ranges of bleaching agent recited in the claims, Applicants cite to MPEP § 716.02(d), which states that "the nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the provative value thereof". *In re Kollman*, 595 F.2d 48, 56 201 USPQ 193 (CCPA 1979); *In re Lindner*, 457 F.2d 506, 509, 173 USPQ 356, 359 (CCPA 1972); *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980).

First, Applicants submit that the range of 10-15% bleaching agent recited in claims 45, 91 and 93 is supported by a trend found in the comparative test results. The Examiner acknowledges that "applicants' declaration ... shows [unexpected] results for ranges of peroxide being 10% or 15%". Office Action, page 7. Because similar unexpected results were achieved relative to reduced sensitivity when the bleaching agent is included in amounts of 10% and 15%, respectively, there would no reasonable basis to argue that concentrations between 10% and 15% would not also possess the same or similar unexpected results relative to reduced sensitivity. The data set forth above in Table 1 clearly show that lowering the potassium nitrate from 3% (compositions B-D) to 0.5% (composition E) had by far the greatest impact on reducing tooth sensitivity. For example, the percent of total days of sensitivity to hot or cold experienced by the test participants dropped from 17.3-23.9 (compositions B-D) to 5.3 (test sample E). In contrast, increasing the amount of dental bleaching composition from 10% (compositions B and C) to 15% (composition D), a 50% increase in the amount of bleaching agent, did not have much of an effect on sensitivity compared to reducing the amount of potassium nitrate to below 3%. For

example, the percent of total days of sensitive to hot or cold was 23.3% for composition C and 23.9 for composition D. From this, one of skill in the art would conclude that increasing the amount of dental bleaching composition from 10% to 15% would not compromise the sensitivity-reducing effect of using an amount of potassium nitrate (*e.g.*, about 0.5%) as recited in the claims. In other words, it is the amount of potassium nitrate, not the amount of bleaching agent, which is the result-effective variable shown by the test data. In view of this, Applicants submit that claims 45, 91 and 93 are patentable over the claims of the '370 patent because they claim a narrow range of bleaching agent (10-15%) that is commensurate in scope with the comparative study (*i.e.*, 10%, 10.5% and 15%).

The next range to consider is found in claims 44, 59, 77, 86 and 92, which claim 10% to about 20% by weight dental bleaching agent. The comparative test showed that when the amount of bleaching agent is increased from 10% to 15%, the same or similar results relative to sensitivity were obtained. This demonstrates a clear trend that altering the amount of dental bleaching agent from 10% to 15%, which is a 50% increase, did not significantly affect or alter the sensitivity results shown by the comparative study. From that trend, it is reasonable to conclude that further increasing the amount of dental bleaching agent from 15% to about 20%, which is only a 33% increase, would not significantly affect or alter the unexpected results shown by the comparative study. Moreover, the comparative study showed that the quantity of potassium nitrate was the result-effective variable, not the amount of bleaching agent. In view of this, Applicants submit that claims 44, 59, 77, 86 and 92 are patentable over the claims of the '370 patent because they claim a narrow range of bleaching agent (10% to about 20%) that is commensurate in scope with the comparative study (*i.e.*, 10%, 10.5% and 15%).

The last range to consider is found in the remaining claims, which claim 10% to about 30% by weight dental bleaching agent. The comparative test showed that when the amount of bleaching agent is increased from 10% to 15%, the same or similar results relative to sensitivity were obtained. This demonstrates a clear trend that altering the amount of dental bleaching agent from 10% to 15% did not significantly affect or alter the sensitivity results shown by the comparative study. From that trend, it is reasonable to conclude that further increasing the amount of dental bleaching agent from 15% to about 30%, would not significantly affect or alter the unexpected results shown by the comparative study. Moreover, the comparative study showed that the quantity of potassium nitrate was the result-effective variable, not the amount of bleaching agent. In view of this, Applicants submit that the remaining claims are patentable over

the claims of the '370 patent because they claim a narrow range of bleaching agent (10% to about 30%) that is commensurate in scope with the comparative study (*i.e.*, 10%, 10.5% and 15%).

Applicants also wish to point out that there is no evidence in the record showing that using different amounts of bleaching agent would affect the desensitizing effect of using a reduced quantity of potassium within the claimed ranges. Applicants did not test, nor were they required to test, whether altering the amount of bleaching agent would affect sensitivity more than reducing the amount of potassium nitrate. The comparative study established that the quantity of potassium nitrate was the result-effective variable, not the amount of bleaching agent. On the other hand, the finding that the claims are not commensurate in scope with the results of the comparative study is based solely on the Examiner's opinion. The Examiner has provided no supporting evidence that the comparative data showing unexpected results would only work for 10% and 15% bleaching agent, not within the claimed ranges. It is well established that a *prima facie* showing of obviousness must be based on evidence in the record, not an examiner's personal opinion.

Finally, Applicants submit that the '370 patent teaches away from the claimed invention, particularly with respect to the narrowly tailored ranges of potassium nitrate. According to the court in *In re Baird*, 16 F.3d 380, 383 (Fed. Cir. 1994), "a reference must be considered not only for what it expressly teaches, but also for what it fairly suggests.... A disclosure of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference leading away from the claimed compounds."

The claims of the instant Application are patentable over the claims of the '370 patent because the '370 patent clearly teaches a preference for using at least 3% by weight of potassium nitrate. It does this by teaching that

the inventive compositions may preferably include potassium nitrate in a wide range from about 0.1% to about 50% by weight of the whitening composition, more preferably in a range from about 1% to about 25% by weight of the whitening composition, and most preferably in a range from about 3% to about 10% by weight of the whitening composition.

Col. 6, lines 53-59 (emphasis added).

Moreover, all but two of the sixteen examples set forth in the '370 patent include 3% or more potassium nitrate, thus further signaling a clear preference for using more potassium nitrate than what is claimed in the instant Application. In contrast, all of the examples in the instant application where superior desensitization was found or was predicted include 2% or less potassium nitrate (*i.e.*, Examples 2-10). Only the comparative examples showing increased sensitivity included either 3% or no potassium nitrate. In view of the clear preference in the '370 patent for using greater amounts of potassium nitrate, one of skill in the art would not have been motivated to deviate from the teachings of the '370 patent and instead select lesser amounts of potassium nitrate within the narrowly tailored ranges recited in the instant claims.

### **III. REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

The Office Action rejects claims 72-85 under 35 U.S.C. § 112, first paragraph, on the grounds that the phrase "without brushing" is new matter. In response, Applicants point out that claim 17 of the originally filed application claimed "[a] dental bleaching composition adapted for whitening and desensitizing a person's teeth without brushing or scrubbing". Application, page 36. The claims of an application form part of the written description and provide support for all that they disclose. Because the Applicants originally disclosed a dental bleaching composition adapted for whitening and desensitizing a person's teeth without brushing or scrubbing in original claim 17, it follows that Applicants were likewise in possession of the method of using such a composition. Accordingly, Applicants submit that claims 72-85 do not claim new matter.

The Office Action rejects claims 41-42, 44-48, 50-87 and 91-93 under 35 U.S.C. § 112, first paragraph, on the grounds that the term "about" before certain of the claimed range endpoints is new matter. More specifically, the alleged new matter consists of claiming range endpoints for the dental bleaching agent of *about* 10%, *about* 15% and a range of *about* 0.5% potassium nitrate. With regard to about 0.5% potassium nitrate, Applicants respectfully point out that this amount was disclosed in claim 3 of the originally filed Application. Application, page 33 ("wherein the potassium nitrate is included in an amount of *about* 0.5% by weight of the dental bleaching composition") (emphasis added). With regard to "about 10%" and "about 15%" Applicants have amended the claims to remove the term "about" before these range endpoints.

In view of the foregoing, Applicants submit that the claims as now presented fully satisfy the requirement of 35 U.S.C. § 112, first paragraph, and do not claim any new matter.



In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 2nd day of June 2009.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J.M. Gynn", is written over the typed name.

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